



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/666,890 09/20/00 HARTLEY

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HM12/1019
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EXAMINER

WHISENANT, F

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/666,890

Applicant(s)

HARTLEY, JAMES L.

Examiner

Ethan C. Whisenant, Ph.D.

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-32 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The applicant's Response to the Office Action has been entered. The applicant's response was received on 7 JAN 97 and has been entered as paper no. 3. The claims pending in this application are Claims 1-13. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

SEQUENCE RULES

2. This application fails to comply with the sequence rules. See the attached notice to comply with the sequence rules. It is noted that this application is a divisional of USSN 08/196,003 wherein the applicant has complied with the sequence rules. The applicant may request to use the CRF from that application using the attached sample statement as a guide.

35 USC § 112- 2ND PARAGRAPH

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

4. Claim(s) 15-32 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 31 are indefinite because it is unclear if only three fragments in the composition need to be (in base pairs) approximately a multiple of an integer or, in the alternative, if each and every fragment in the composition need to be (in base pairs) approximately a multiple of an integer. Also, it is unclear from the claim language if the integer must be the same for every fragment, or in the alternative, if the integer may be different for each fragment.

35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 102/103

8. Claim(s) 15-22 is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carlson et al. [EP466404A1(1991)].

Claim 15 is drawn to a nucleic acid marker ladder which comprises at least 3 nucleic acid fragments wherein the size of each of said fragments in base pairs is approximately a multiple of an integer.

Carlson et al. teach a nucleic acid marker ladder which comprises at least 3 nucleic acid fragments (i.e. 730, 910 and 2650) wherein the size of each of said fragments in base pairs is approximately a multiple of an integer. See Figure 1.

Please note that even if the claims are read more narrowly wherein the phrase "each of said fragments" refers to each and every fragment in the marker ladder composition, Carlson et al would still read on it because these authors teach fragments (in base pairs) that are **approximately** a multiple of an integer. Also note that the word integer has been accorded its "usual" meaning {i.e. integer [in't jr] Mathematics. a positive or negative whole number or zero; an element of the set { . . . , -2, -1, 0, 1, 2, . . . }}. This definition was obtained from The Academic Press Dictionary of Science and Technology.

Claim 16 is drawn to an embodiment of Claim 15 wherein said at least 3 nucleic acid fragments result from the digestion of a nucleic acid by one or more restriction enzymes.

Carlson et al. teach this limitation. See, for example the abstract.

Claim 17 is drawn to an embodiment of Claim 16 wherein said at least 3 nucleic acid fragments are generated simultaneously in one reaction.

Admittedly, Carlson et al do not explicitly teach this limitation (i.e. wherein the 730, 910 and 2650 bands) are generated simultaneously in one reaction. However, a product is not limited by the why it is made but rather by its structure. If the product in a claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim 18 is drawn to an embodiment of Claim 15 wherein said integer is approximately 10 or more.

Carlson et al. teach this limitation. For example: 730 is a multiple of the integer 10 (i.e. an integer that is approximately 10 or more). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 10 or more) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 10 or more).

Claim 19 is drawn to an embodiment of Claim 18 wherein said integer is approximately 10.

Carlson et al. teach this limitation. For example 730 is a multiple of the integer 10 (i.e. an integer that is approximately 10). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 10) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 10).

Claim 20 is drawn to an embodiment of Claim 18 wherein said integer is approximately 25.

Carlson et al. teach this limitation. For example, 730 is a multiple of the integer 10 (i.e. an integer that is approximately 25). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 25) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 25).

This rejection has been applied in view of the use of the phrase "approximately a multiple of an integer" in Claim 15 and the phrase "wherein said integer is approximately 25" in Claim 20.

Claim 21 is drawn to an embodiment of Claim 18 wherein said integer is approximately 50.

Carlson et al. teach this limitation. For example, 730 is a multiple of the integer 10 (i.e. an integer that is approximately 50). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 50) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 50).

This rejection has been applied in view of the use of the phrase "approximately a multiple of an integer" in Claim 15 and the phrase "wherein said integer is approximately 50" in Claim 21.

Claim 22 is drawn to an embodiment of Claim 18 wherein said integer is approximately 100.

Carlson et al. teach this limitation. For example, 730 is a multiple of the integer 10 (i.e. an integer that is approximately 100). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 100) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 100).

This rejection has been applied in view of the use of the phrase "approximately a multiple of an integer" in Claim 15 and the phrase "wherein said integer is approximately 100" in Claim 22.

Claim 23 is drawn to a nucleic acid marker kit comprising a carrying means having in close confinement therein at least one container means wherein said container means contains a nucleic acid marker ladder which comprises at least 3 nucleic acid fragments wherein the size of each of said fragments in base pairs is approximately a multiple of an integer.

Carlson et al. teach a nucleic acid marker ladder which comprises at least 3 nucleic acid fragments (i.e. 730, 910 and 2650) wherein the size of each of said fragments in base pairs is approximately a multiple of an integer. See Figure 1. Carlson et al also teach a kit comprising a container means which contains their nucleic acid marker ladder. See, for example p.3 beginning at about line 20.

Claim 24 is drawn to an embodiment of Claim 23 wherein said at least 3 nucleic acid fragments result from the digestion of a nucleic acid by one or more restriction enzymes.

Carlson et al. teach this limitation. See, for example the abstract.

Claim 25 is drawn to an embodiment of Claim 24 wherein said at least 3 nucleic acid fragments are generated simultaneously in one reaction.

Admittedly, Carlson et al do not explicitly teach this limitation (i.e. wherein the 730, 910 and 2650 bands are generated simultaneously in one reaction). However, a product is not limited by the way it is made but rather by its structure. If the product in a claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim 26 is drawn to an embodiment of Claim 23 wherein said integer is approximately 10 or more.

Carlson et al. teach this limitation. For example: 730 is a multiple of the integer 10 (i.e. an integer that is approximately 10 or more). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 10 or more) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 10 or more).

Claim 27 is drawn to an embodiment of Claim 26 wherein said integer is approximately 10.

Carlson et al. teach this limitation. For example: 730 is a multiple of the integer 10 (i.e. an integer that is approximately 10). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 10) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 10).

Claim 28 is drawn to an embodiment of Claim 26 wherein said integer is approximately 25.

Carlson et al. teach this limitation. For example 730 is a multiple of the integer 10 (i.e. an integer that is approximately 25). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 25) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 25).

This rejection has been applied in view of the use of the phrase "approximately a multiple of an integer" in Claim 23 and the phrase "wherein said integer is approximately 25" in Claim 28.

Claim 29 is drawn to an embodiment of Claim 26 wherein said integer is approximately 50.

Carlson et al. teach this limitation. For example, 730 is a multiple of the integer 10 (i.e. an integer that is approximately 50). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 50) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 50).

This rejection has been applied in view of the use of the phrase "approximately a multiple of an integer" in Claim 23 and the phrase "wherein said integer is approximately 50" in Claim 29.

Claim 30 is drawn to an embodiment of Claim 26 wherein said integer is approximately 100.

Carlson et al. teach this limitation. For example, 730 is a multiple of the integer 10 (i.e. an integer that is approximately 100). 910 is a multiple of the integer 10 (i.e. an integer that is approximately 100) and 2650 is a multiple of the integer 10 (i.e. an integer that is approximately 100).

This rejection has been applied in view of the use of the phrase "approximately a multiple of an integer" in Claim 23 and the phrase "wherein said integer is approximately 100" in Claim 30.

ALLOWABLE SUBJECT MATTER

- 9.** Claims 31-32 appear to be allowable over the prior art of record.

CLAIM OBJECTIONS

- 10.** Claim(s) 33 is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

- 11.** Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.


CONCLUSION

- 12.** Claim(s) 15-33 is/are rejected and/or objected to for the reason(s) set forth above.
- 13.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, PhD. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

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The fax number for this Art Unit is (703) 308-8724. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.


ETHAN C. WHISENANT
PRIMARY EXAMINER

10/15/01

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

7. Other: _____

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as, an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

Sample Statement

Sample Request to Use Computer Readable Form from Another Application

The following paragraph, or language having the same effect, can be used to invoke the procedures of 37 CFR section 1.821(e) in which an identical computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application.

The computer readable form in this application 08/100,000, is identical with that filed in Application Number 07/999,999, filed March 1, 1988. In accordance with 37 CFR 1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately-filed preliminary amendment for incorporation into the specification, whichever is applicable]